UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,551	08/07/2006	Stig Ollmar	P08984US01/BAS	8295

881 7590 01/21/2011

STITES & HARBISON PLLC
1199 NORTH FAIRFAX STREET
SUITE 900
ALEXANDRIA, VA 22314

EXAMINER	
D'ANGELO, MICHAEL J	

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
01/21/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

iplaw@stites.com

Office Action Summary	Application No.	Applicant(s)	
	10/588,551	OLLMAR ET AL.	
	Examiner	Art Unit	
	MICHAEL D'ANGELO	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *79,80,82,86-93 and 95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *79,80,82,86-93 and 95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed on 11/29/2010 has been acknowledged

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

2. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 79, 82, 91, and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caduff et al. (US 7,315,767) in view of Bauer (US 6,322,963).

Regarding claim 79, Caduff discloses a system for measuring the impedance through subcutaneous tissue and correlating that impedance to a blood glucose level (column 2 lines 10-55) comprising an injection electrode and sensing electrode (electrodes 18 and 19) for injecting a current into the body and sensing the voltage caused by the current (column 2 lines 39-47), a means for measuring the impedance and processor for correlating the impedance with a relationship between the impedance and glucose level and for calculating the blood glucose level (column 7, lines 4-17), but fails to disclose the use of a pair of injection and sensing electrodes.

However, Bauer disclose a glucose measuring system that uses impedance as a measurement parameter based on the voltage applied between an injection and sensing electrode (column 12 line 50 to column 13 line 1), and further discloses that the sensing system (i.e. sensing and injection electrode) may be duplicated (i.e.

multiplexed) (column 17, lines 58-62, the examiner notes that if multiple sensor strips are used there would be pairs of injection and sensing electrodes present).

4. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the electrode system of Caduff to include using pairs of injection and sensing electrodes as taught by Bauer in order to reduce the likelihood of false readings.

Regarding claim 82, Caduff discloses the tissue being blood vessels (column 1 lines 35-39.

Regarding claims 91 and 93, Caduff discloses the use of a visual display for indicating the calculated blood glucose (display 11).

5. Claims 86 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caduff et al. (US 7,315,767) in view of Bauer (US 6,322,963) and further in view of Purvis et al. (US 2004/ 0182719).

6. **Regarding claims 86 and 87,** Caduff as modified by Bauer discloses a source of electrical current connected to the injection electrodes (VCO 1 of Caduff), and where the electrical current is provided at an array of frequencies between 1Hz and 10 MHz (column 4 lines 30-31 of Caduff), but fails to disclose an amperometer or a voltmeter, wherein the amperometer and current source are connected to the injection electrodes and the voltmeter is connected to the sensing electrodes.

7. However, Purvis discloses an amperometer and a voltmeter (paragraph 5, lines 9-11 and paragraph 12, lines 1-4), wherein the amperometer and current source are

connected to the injection electrodes and the voltmeter is connected to the sensing electrodes (paragraph 5, lines 9-11 and paragraph 12, lines 1-4).

8. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a physiological monitor similar to that of Caduff, as modified by Bauer to include an amperometer and a voltmeter, wherein the amperometer and current source are connected to the injection electrodes and the voltmeter is connected to the sensing electrodes, as taught by Purvis, in order to control the voltage and sense the voltage/current.

9. Claims 80, 88-89 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caduff et al. (US 7,315,767) in view of Bauer (US 6,322,963) and further in view of Steil et al. (US 2003/0130616).

Regarding claims 80, Caduff as modified by Bauer fails to disclose where at least one pair of electrodes is adapted for inserting into body tissue.

However, Steil discloses glucose monitoring electrodes located within the subcutaneous tissue (see figure 3).

10. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify an electrode configuration similar to that of Caduff as modified by Bauer to have the electrodes subcutaneously implanted in order to provide accurate conduction of the voltage through the patient tissue.

11. **Regarding claims 88-89 and 92,** Caduff as modified by Bauer fails to disclose that the microprocessor is operatively connected to an insulin pump and includes means to adjust the amount of insulin flow via the pump to the subject based on the

determined glucose level, a means for calibrating the apparatus against a directly measured glucose, or the apparatus is implanted in the body tissue for which the impedance is to be measured.

However, Steil discloses that the microprocessor is operatively connected to an insulin pump and includes means to adjust the amount of insulin flow via the pump to the subject based on the determined glucose level (abstract, view figure 1, paragraph 98, lines 30-35), a means for calibrating the apparatus against a directly measured glucose level (paragraph 248, lines 1-8, view figure 32), and the apparatus is implanted in the body tissue for which the impedance is to be measured (paragraph 318, lines 1-4).

12. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a physiological monitor similar to that of Caduff as modified by Bauer to include the microprocessor operatively connected to an insulin pump and means to adjust the amount of insulin flow via the pump to the subject based on the determined glucose level, a means for calibrating the apparatus against a directly measured glucose, and implant the apparatus in the body tissue for which the impedance is to be measured in order to provide a system that can easily notify the user of their glucose levels as well as provide a means for keeping the user's glucose in a healthy range therefore increasing safety.

13. Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caduff et al. (US 7,315,767) in view of Bauer (US 6,322,963) and further in view of Abreu (US 2002/0049389).

14. **Regarding claim 90,** Caduff as modified by Bauer fails to disclose that the processor is programmed to determine the glucose level based on a principal component analysis and a partial least square regression analysis.

However, Abreu discloses a processor programmed to determine the glucose level based on a principal component analysis and a partial least square regression analysis (paragraph 296, lines 6-8, the examiner notes that although the disclosure of Abreu is not directed toward using skin impedance the use of principal component analysis and a partial least square regression taught by Abreu can be applied to any physiological signal to reduce processing variability).

15. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a physiological monitor similar to that of Caduff, as modified by Bauer to determine the glucose level based on a principal component analysis and a partial least square regression analysis as taught by Abreu in order to reduce variability due to tissue structure.

16. Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caduff et al. (US 7,315,767) in view of Bauer (US 6,322,963) and further in view of Ollmar et al. (US 2003/0220581).

Regarding claim 95, Caduff as modified by Bauer fails to disclose an impedance depth between 0.1-2mm.

However, Ollmar discloses measuring impedance using the Scibase II (paragraph 112, the examiner notes that in the applicant's specification on page 11 lines 2-4 it is cited that the Scibase II is used to measure impedance at a depth range of 0.1-

2 mm. Ollmar discloses using the Scibase II therefore it can be said to meet the limitation of the required depth).

17. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a physiological monitor similar to that of Caduff, as modified by Bauer to incorporate an impedance depth between 0.1-2mm as taught by Ollmar in order to provide a device that can vary the penetration depth, providing a more accurate system.

Response to Arguments

Applicant's arguments with respect to claim 79 have been considered but are non persuasive. The examiner agrees with the applicant that the combination can be made to show that the sensor structure of Caduff can be duplicated such that two identical devices are used simultaneously to make the glucose reading. However, the examiner disagrees that this would not read on the limitation of having a pair of injection electrodes and a pair of sensing electrodes. No where does claims 79 recite that the pair of sensing electrodes work ***together*** to detect the voltage caused by the injection electrodes or that the pair of sensing electrodes are located on the same body or housing which would preclude redundant devices used together. The examiner contends that two pair of one to one injection and sensing electrodes would still me the limitation as currently written. Based on this the additional arguments as to modifying the specified structure of Caduff and that the combination would be improper due to differing sensing means are moot.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL D'ANGELO whose telephone number is (571) 270-7112. The examiner can normally be reached on Monday-Friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/M. D./
Examiner, Art Unit 3735